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# A phase II, randomised, double-blind, placebo-controlled pilot study of the safety, tolerability and activity of intramuscularly administered a-Epi-Br (HE2000) in late stage human immunodeficiency virus-infected patients at risk for opportunistic infections

**Submission date**
06/04/2006

**Registration date**
15/05/2006

**Last Edited**
16/10/2009

**Recruitment status**
No longer recruiting

**Overall study status**
Completed

**Condition category**
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

### Secondary identifying numbers
HE2000-006.4

# Study information

### Scientific Title

### Study objectives
1. To evaluate the safety and tolerability of up to seven treatment courses of 100 mg of HE2000
2. To evaluate the effect of HE2000 on the incidence rate, time to resolution and time to recurrence of opportunistic infections in late stage human immunodefiency virus (HIV)-infected patients
3. To assess the effect of repeated administrations of HE2000 (a total of 7 treatment courses) on quality of life
4. To assess the effect of HE2000 on the immune system

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved by the Medicines Control Council on 26/09/2000, reference number: N2/19/8/2 (1666)

### Study design
Randomised double-blind placebo-controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied
Human immunodeficiency virus (HIV)

### Interventions
The treatment course consisted of intramuscular injections, once daily for five days, of either 100 mg of HE2000 or placebo in the control group, followed by a 37-day observation period (6 weeks), for up to seven courses

### Intervention Type
Drug

### Phase
Not Specified

### Drug/device/biological/vaccine name(s)
HE2000

### Primary outcome measure
To evaluate the safety and tolerability of up to seven treatment courses of 100 mg of HE2000 administered intramuscularly in late HIV patients

### Secondary outcome measures
The assessment of the effect of HE2000 on the incidence rate of opportunistic infections

### Overall study start date
20/11/2000

### Completion date
02/12/2002

## Eligibility

### Key inclusion criteria
1. HIV-infected patients who are at least 18 years old with a CD4 cell count ≤100 cell/mm^3 and who are at risk for developing opportunistic infections
2. Karnofsky Performance Score of at least 60 and a life expectancy of at least 6 months

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
40

### Key exclusion criteria
1. Patients who have received treatment with chemotherapeutic agents within four weeks of study screen
2. Patients receiving immunomodulatory therapies including interferon, interleukins or steroids (e.g. Moducare, testosterone, deca-durabolin, Dehydroepiandrosterone [DHEA], oxandrolone) within four weeks of the screening visit
3. Patients receiving metabolic inhibitors (e.g. hydroxyurea, cyclophosphamide, methotrexate) within four weeks of the screening visit

4. Patients who are deficient in glucose-6-phosphate dehydrogenase (G6PDH) enzyme
5. Patients with an active, opportunistic infection (OI) requiring acute intervention (i.e. hospitalization) within two weeks of screening; (patients undergoing prophylactic OI treatment or completing OI treatment after resolving the acute phase of the infection are permitted entry in the discretion of the investigator)
6. Patients currently diagnosed, with malignancy including invasive cervical cancer (based on pelvic exam and PAP smear), lymphoma (based on observation and patient history), progressive cytomegalovirus (CMV) disease including CMV-retinitis (based on ophthalmic exam including funduscopy, patient history), Kaposi's sarcoma with visceral involvement (based on physical examination and patient history), HIV-encephalopathy and
acquired immune deficiency syndrome (AIDS)-related dementia (based on investigators judgment and patient history)
7. Patients who have acute tuberculosis (TB) or malaria based on laboratory results
8. Patients who have malaria (based on laboratory results)
9. Patients with a malignancy other than cutaneous Kaposi's sarcoma (KS) or basal cell carcinoma
10. Patients with biopsy-confirmed cutaneous KS are eligible at the discretion of the investigator
11. Patients must not have received any systemic therapy for KS within four weeks prior to the screening visit and are not anticipated to require systemic therapy during the course of the study
12. Patients with a clinical condition or receiving therapy that, in the opinion of the investigator, would make the patient unsuitable for study or unable to comply with the dosing requirements
13. Patients who are breast feeding

### Date of first enrolment
20/11/2000

### Date of final enrolment
02/12/2002

## Locations

### Countries of recruitment
South Africa

### Study participating centre
**Karl Bremmer Hospital**
Cape Town
South Africa
7531

## Sponsor information

### Organisation
Hollis-Eden Pharmaceuticals, Inc. (USA)

### Sponsor details

4435 Eastgate Mall
Suite 400
San Diego
United States of America
92121

**Sponsor type**
Industry

**Website**
http://www.holliseden.com

# Funder(s)

**Funder type**
Industry

**Funder Name**
Hollis-Eden Pharmaceuticals, Inc. (USA)

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration